2012

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Recommended Citation

Fabiszewski de Aceituno, A.M., C.E. Stauber, A.R. Walters, R.E. Meza Sanchez, and M.D. Sobsey. 2012. A Randomized Controlled Trial of the Plastic-Housing BioSand Filter and its Impact on Diarrheal Disease in Copan, Honduras. American Journal of Tropical Medicine and Hygiene, 86(6): 913-921.

Am. J. Trop. Med. Hyg., 86(6), 2012, pp. 913–921
doi:10.4269/ajtmh.2012.11-0066

A Randomized Controlled Trial of the Plastic-Housing BioSand Filter and Its Impact on Diarrheal Disease in Copan, Honduras

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Abstract. Point of use drinking water treatment with the BioSand filter (BSF) allows people to treat their water in the home. The purpose of this research was to document the ability of the Hydraid plastic-housing BSF to reduce diarrheal disease in households who received a BSF in a randomized controlled trial. The trial of the Hydraid plastic-housing BSF was carried out in rural, mountainous communities in Copan, Honduras during April of 2008 to February of 2009. A logistic regression adjusting for clustering showed that the incidence of diarrheal disease in children under 5 years was reduced by approximately 45% (odds ratio = 0.55, 95% confidence interval = 0.28, 1.10) in households that had a BSF compared with those households without a BSF, but this finding fluctuated depending on season and was not statistically significant. Households with a BSF had significantly better drinking water quality regardless of water source or season.

INTRODUCTION

Diarrheal disease accounts for 16% of deaths in children under 5 years, nearly 1.5 million per year, which is more than human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), malaria, and measles combined.[1] Over 88% of diarrheal disease can be attributed to lack of clean water, sanitation, or hygiene.[2] Unfortunately, as of 2008, 884 million people still lack access to improved sources of drinking water and must drink unimproved water or treat water for themselves.[3] Even more lack safe drinking water; many improved drinking waters are unsafe, because they contain unacceptably high levels of fecal bacteria indicative of the presence of enteric pathogens. Increasing access to safe water with conventional infrastructure takes many years, and even when infrastructure is present, it can be difficult to operate and maintain for continuous safe water provision. One option to bridge the gap between use of unsafe water and effective municipal infrastructure is point of use (POU) water treatment in the home or at other community gathering points. Studies of household water treatment (HWT) at the POU have shown that it can reduce the risk of diarrheal disease on average by 35% and can reduce the risk of diarrheal disease more than source water treatment alone.[4,5]

One promising POU technology is the BioSand filter (BSF), an adaptation of slow sand filtration to a household scale, that is intermittently operated in a concrete or plastic housing.[6] The advantages of the BSF are a simple design, durability, little maintenance and recurring capital investments, local fabrication of the concrete housing, and a rapid flow rate (15–45 L/hour) that can provide quantities of water.[7] The concrete-housing BSF has a been found to have sustained use of 87.5% even years after installation.[8,9] As of 2007, over 140,000 concrete-housing BSFs had been distributed globally.[10] Field studies have shown 87–98% mean reductions in *Escherichia coli* by the concrete-housing BSF in households in diverse geographic locations.[8,9,11] Reductions in diarrheal disease of 40% or greater with the use of the concrete-housing BSF have been documented in Cambodia, the Dominican Republic, and Kenya.[9,12,13]

Limitations of the concrete-housing BSF include its slower rate of daily production by a laborious process and the housing weight of several hundred pounds, making it difficult to transport to remote locations where the BSF is often needed most.[8] Plastic-housing BSFs may overcome these problems in production, distribution, and transport, because the lightweight housing can be mass produced using injection molding and nested for bulk transport. Because of some design differences from the concrete filter, such as a smaller surface area, tapered wall, and smaller sand bed volume, it is uncertain that the plastic-housing BSF will have the same performance characteristics as the concrete versions.

This trial is the first known randomized controlled trial (RCT) of the plastic-housing BSF that studies its ability to improve water quality and reduce diarrheal disease. This study was one of three randomized controlled trials conducted simultaneously in Honduras, Ghana, and Cambodia with the goal of assessing the ability of the Hydraid plastic-housing BSF (Cascade Engineering, Inc., Grand Rapids, MI) to improve water quality and reduce diarrheal disease across cultures, climates, and drinking water conditions.

The Hydraid filter technology is currently owned by Cascade Engineering. The filter tested in this study was Version 2 of the Hydraid BSF and was produced and distributed by International Aid, a non-governmental relief organization. Since the installation of the BSFs in this study, Cascade Engineering has purchased the technology and made several structural changes to the Hydraid BSF design.

In Honduras, 92% of the urban population but only 67% of the rural population has access to piped water near their home, whereas 43% use some sort of household water treatment.[14] Determining the effectiveness of the plastic-housing BSF in Honduras is important, because many concrete and plastic-housing BSFs are already in place throughout the country. Samaritan's Purse Latin America Water Program installed nearly 6,000 concrete BSFs between 2007 and 2010 alone (Sanchez Sotomonte C, written communication), whereas International Aid Honduras had installed over 2,000 plastic-housing Hydraid BSFs as of June 2008 (Meza R, written communication). The purpose of this study was to evaluate the ability of the Hydraid plastic-housing BSF to improve

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the microbial quality of drinking water and reduce diarrheal disease in children less than 5 years of age living in communities in rural western Honduras using unimproved drinking water sources.

METHODS

Research setting, study population, and participant recruitment. This study was conducted in 11 rural communities in the municipalities of Santa Rosa de Copan, Cucuyagua, San Juan, and San Jose in the Copan Department of western Honduras. Field data collection took place between April of 2008 and February of 2009. Communities were recruited if they were within 1 hour driving distance of the study laboratory in Santa Rosa, did not have year-round access to piped water, and had at least 10 families with children under 5 years old. Inclusion criteria for study participation were community and individual willingness to participate, a child less than 5 years old living in the household, and no use of bottled water as the primary source of drinking water. Households were excluded if they used bottled water as their drinking water source, did not have a child less than 5 years of age, or did not want to participate. Communities were approached until 195 households had agreed to participate, provided informed consent, and were enrolled in the study. The number of households recruited was based on an initial sample size calculation to detect a 25% difference in diarrheal disease with 95% confidence between children under 5 years of age in control and BSF intervention households, assuming a 7-day diarrheal disease prevalence of 10% and 80% statistical power.[15–17]

Study design and protocols were approved by the Institutional Review Board (IRB) of the University of North Carolina at Chapel Hill (IRB #08-0063) and the Ethics Committee of Biomedical Investigation at the National Autonomous University of Honduras. Informed consent was obtained from the primary respondent during the initial household visit who was defined as the primary caretaker for the children and responsible for household water management practices (usually an adult female). An initial cross-sectional study in all communities took place April 14–30, 2008. The purpose of the initial phase was to collect data on diarrheal disease prevalence at the household level as well as potential risk factors of diarrheal disease, including socioeconomic status, education, knowledge about diarrheal disease, and access to water sources and sanitation. After the cross-sectional study, all 195 households that met the inclusion criteria were asked to participate in the longitudinal phase of the RCT of the plastic-housing BSF; all but one household chose to participate.

Intervention. After completing the initial phase, the household visits for the longitudinal portion of the RCT were administered between May 5, 2008 and February 25, 2009. Households were visited biweekly for 3.5 months (seven visits) before randomization into BSF intervention and control groups. The purpose of the pre-intervention data collection was to characterize and compare diarrheal disease and water quality between what would become the randomly selected intervention (plastic-housing BSF) and control (no BSF) study groups. Before the intervention, research staff collected biweekly information on water source, water management practices, and diarrheal disease for each household. A sample of drinking water was collected at each visit to characterize drinking water quality.

The randomization of households and installation of plastic-housing BSFs took place August 11–20, 2008. Households were unaware whether they would be assigned to the intervention (plastic-housing BSF) or control (no BSF) group until 1 day before installation. Households were randomized by random number generation; 90 households were selected to receive plastic-housing BSFs and 86 families were selected to remain in the control group. The International Aid Honduras BSF installation team provided training for the use and maintenance of the plastic-housing BSF and general education about hygiene and sanitation to representatives of each participating family in a community meeting 1 day before BSF installations. The families who were selected to receive a plastic-housing BSF were announced after the education session, and the next day, an International Aid employee, supervised by a member of the study field staff, installed the plastic-housing BSF and reviewed its operation and maintenance with the family members. In addition to the plastic-housing BSF, the BSF intervention group households received a narrow-mouth 5-gallon (~20 L) water jug in which to store filtered water, and flexible tubing was installed on the outflow pipe of the BSF to direct the filtered water into the storage container. Families who received the plastic-housing BSF were reminded that they were still free to leave the study for any reason at any time but that the BSF would be removed from the home if they left the study.

After plastic-housing BSF installation, field staff continued to visit households biweekly for 6 months (13 visits) from August 28, 2008 to February 25, 2009. Control households continued their previous water management practices and were administered the same interview as during the baseline observation period. The intervention households were, in addition to the pre-intervention questionnaire, asked about their use and maintenance of the plastic-housing BSF during each of the biweekly household visits of the intervention period.

Diarrheal disease surveillance. A standard system of diarrheal disease surveillance was incorporated into the bimonthly longitudinal in-home study questionnaires. On beginning the cross-sectional study period, the primary respondent completed the biweekly questionnaires for the longitudinal study. The primary respondents were asked to verbally report any occurrence of diarrhea in the household within the last 7 days. If a person was identified as having diarrhea, the following information was requested: duration and onset of disease, maximum number of evacuations in 24 hours, stool consistency, and presence of blood in the stool. Field staff recorded all reports of diarrhea that met the World Health Organization (WHO) definition: passage of three or more loose or liquid stools per day.[18] If the diarrhea was ongoing as of the date of the visit, the case was followed-up during the next questionnaire visit. Diarrheal disease data were gathered for all intervention period questionnaires from May 5, 2008 to February 25, 2009. Overall, there were 7 visits before BSF installation and 13 visits after BSF installation for a total of 20 non-consecutive weeks of diarrheal disease observation.

Water quality sample collection and analysis. Samples of drinking water were taken during household visits at both the control and BSF intervention groups, totaling 5 times before and 12 times after plastic-housing BSF installations. After plastic-housing BSF installation, control households also continued to provide a sample of water used for drinking.

Households with plastic-housing BSFs provided three water samples at each visit when available: unfiltered water, water directly from the plastic-housing BSF outlet tube, and BSF-treated water that had been stored for drinking. Water samples were collected by field staff directly from water storage containers or the BSF outlet tube into 500-mL sterile Whirl-Pak sample collection bags. These samples were stored on ice and transported to the Central American Medical Outreach field laboratory in Santa Rosa de Copan, where they were immediately processed. All samples were tested for total coliforms and *E. coli* using the IDEXX Colilert Quantitray System (IDEXX Laboratories, Westbrook, ME) according to the manufacturer's instructions. Most probable number (MPN) concentrations for total coliforms and *E. coli* were determined using the IDEXX-provided MPN table. Turbidity and pH of each water sample were tested using the Hach 2100P Portable Turbidimeter and the Hach sensION1 Portable pH Meter (Hach Company, Loveland, CO).

Average monthly rainfall. Daily rainfall data from the Santa Rosa de Copan airport was retrieved from weatherunderground.com for the entire study period of April of 2008 to February of 2009. Total monthly rainfall (cm/month) was used to classify the seasonal rainfall period, with less than 15 cm/month of rain considered the dry season and more than 15 cm/month of rain considered the rainy season. Based on this classification, during the study period, the rainy season was July to October of 2008, and the dry seasons were April to June of 2008 and November of 2008 to February of 2009.

Data analysis. The effect of the plastic-housing BSF on diarrheal disease rates was determined by comparing the incident cases of diarrhea for each group of the plastic-housing BSF households (intervention) and the non-user households (control). Incidence rates and incidence rate ratios of diarrheal disease were used to look for associations between or among groups (intervention *versus* control and age groups) for diarrheal disease in relation to drinking water quality and other environmental variables. Water quality, health, and other household demographic data were also initially analyzed to identify trends for exposure and outcome variables. The main exposure variable was the presence of a plastic-housing BSF. Additional covariates included drinking water quality and those covariates related to water, sanitation, and hygiene. The outcome variable was diarrheal disease in individuals and specifically, in children under 5 years of age. Logistic regression models were used to analyze the odds of diarrheal disease by exposure status. Potentially confounding variables considered were those variables thought to affect the continued use of the plastic-housing BSF and consumption of filtered water (the exposure) and those variables considered risk factors for diarrheal disease. The following covariates were assessed using backward step-wise elimination: gender, community, access to latrines, education of the caregiver, and wealth as assessed from the cross-sectional interview as well as age, water quality, and season from the longitudinal data. Covariates were selected based on an *a priori* change in effect criterion of 10%.[19] A generalized estimating equation (GEE) extension of the logistic regression model was used to adjust for clustering within households.

Logistic regression was performed using the following covariates: community in which the family resided, type of water source, and ordinal age. Age groups were < 2, 2–4, and 5–89 years of age. The water sources were described by the respondent and categorized as follows: protected source, unprotected spring or surface water, rainwater, or piped water. Protected sources were natural springs that had been protected from contamination by enclosing the water source in concrete and installing a tap. Unprotected springs or surface water sources were unimproved and open to potential contamination. All data analyses were performed in Stata 10.0 (Stata; StataCorp, College Station, TX). All data reported are based on the odds ratios from the logistic regression.

Water quality data were analyzed in Microsoft Excel and Stata 10.0 for graphical presentation and means testing. Data were $\log_{10}$-transformed for *E. coli* and total coliforms. The microbial reductions achieved by the plastic-housing BSF were calculated as $\log_{10}$ reductions: $\log_{10}$ reduction = $\log_{10}$ influent – $\log_{10}$ effluent. Turbidity reductions were calculated in a similar way but without log transformation. Families with plastic-housing BSFs reported sometimes drinking water directly after filtering and sometimes storing their filtered drinking water, and because the microbial concentrations in these two types of water often differed, neither sample in itself was an appropriate approximation of the families' drinking water quality. Therefore, filtered drinking water quality for plastic-housing BSF households was determined by averaging the parameter concentrations in samples taken directly from plastic-housing BSF and stored plastic-housing BSF-treated water. If control households treated their water, drinking water quality was determined by averaging the parameter concentrations of untreated and treated water samples, which was done because families that treated their drinking water reported doing so only for some specific uses (e.g., boiling water for coffee but using untreated water when making powdered drinks). Paired *t* tests were used to compare geometric mean *E. coli* concentrations between groups and seasons, whereas the Kruskal–Wallis test was likewise used to compare sample turbidity data between groups and seasons. A GEE extension of the logistic regression model was used to examine the relationship between the outcome of diarrhea and exposure to $\log_{10}$ MPN/100 mL concentrations of *E. coli* in drinking water adjusted for the categorical age of the study participant and clustering within households.

RESULTS

Study enrollment and completion. Shown in Figure 1 is a timeline of household enrollment and participation in this study. During the pre-intervention period (May–August 2008), 18 households dropped out of the study, because they moved out of the study area, were unable to be present at biweekly visits because of work, or chose not to make the time commitment. Households were randomized on August 5, 2008, and Hydraid plastic-housing BSF installations took place for 90 randomized households from August 11–20, 2008. The remaining 86 households continued with their normal water management as non-intervention controls.

During the intervention period of the longitudinal study, one family in the BSF intervention group dropped out, because they moved out of the community. In the control group, four families left the study: two because of conflicts with their work schedule and two because of moving out of the study area. In total, 98.8% of the intervention households and 95.3% of the control households completed the study.

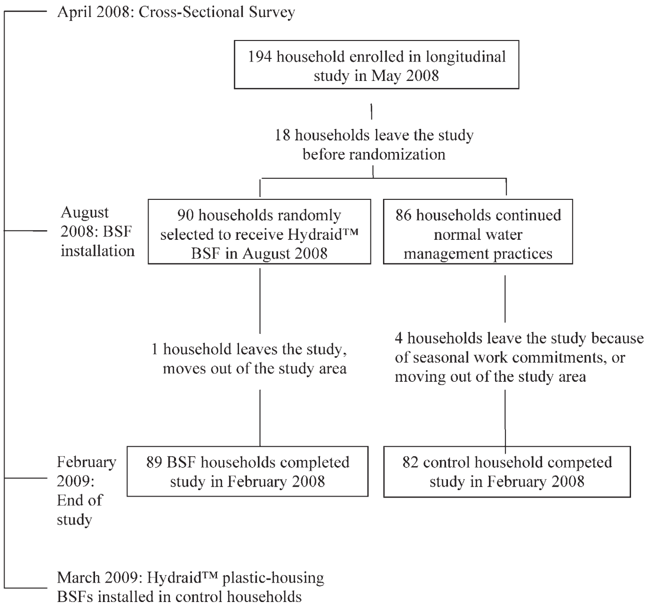

FIGURE 1. Diagram and timeline of household enrollment and participation in a randomized control trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from April of 2008 to February of 2009.

Baseline characteristics and group comparability. For the longitudinal study, there were 532 people in 90 households randomized to the BSF intervention group and 488 people in 86 households randomized to the control group. Tables 1 and 2 show characteristics of the BSF intervention and control groups based on data collected during the initial cross-sectional recruitment. Statistically, the two groups did not significantly differ in age of participants, number of male and female participants, or household size. Intervention and control group characteristics regarding water, sanitation, hygiene, diarrheal disease, education, and socioeconomic status are presented in Table 2. The two groups were not significantly different in their water collection frequency, type of main water source, changes in their water sources during the dry and rainy seasons, or whether reporting that they treated their water. Most households of both groups reported water collection more than five times per week, but < 20% of both household groups reported treating their water before drinking it. The majority of households of both groups did not own a latrine and used open defecation, and one-quarter of the caregivers in each household group had no formal education. Based on an analysis of the following parameters, households were classified into wealth categories: house structure and materials, parents' education, and ownership of animals and durable goods. As a result, 44% of control households and 39% of intervention households were classified in the lower 40% of a wealth distribution index, a difference that was not significant ($P = 0.51$). Furthermore, in the 7 days before the cross-sectional interview, 10.7% of all children under 5 years in the control group and 9.3% of them in the BSF intervention group had diarrheal disease, a difference that was not significant ($P = 0.73$).

Diarrheal disease incidence. The average monthly diarrheal disease incidence rates for intervention and control household children 2–4 years old are shown in Figure 2 and plotted against monthly rainfall data. Diarrheal disease incidence of this child age group decreased in both the BSF intervention and control households during the rainy season (August–November 2008) when the intervention period began. In the dry season (December 2008–February 2009), the incidence of diarrhea in this child age group increased in control households but continued to decrease in intervention households. Similar trends in diarrheal disease relative to rainfall were seen when comparing between groups of children under 5 years of age and individuals of all ages.

Unadjusted incidence rate ratios (IRRs) were calculated to compare the effect of the plastic-housing BSF on household diarrhea by age group and time period as shown in Table 3. Before intervention, households that eventually were randomly

TABLE 1

Age (as of August 2008), household size, and sex of participants in a randomized controlled trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from April of 2008 to February of 2009

	Control (N = 488)	Intervention (N = 532)	P value (Pearson χ^2 test)
Age			
Participants ≥ 5 years	374 (47.7%)	410 (52.3%)	0.78
Participants < 5 years	112 (48.7%)	118 (51.3%)	0.78
Household size			
Range per household	3–12	3–11	
Average per household	5.67	5.91	0.731
Sex			
Male (≥ 5 years)	190 (47.9%)	207 (52.1%)	0.326
Male (< 5 years)	61 (50.8%)	59 (49.2%)	0.326
Female (≥ 5 years)	186 (47.3%)	207 (52.7%)	0.858
Female (< 5 years)	51 (46.4%)	59 (53.6%)	0.858

TABLE 2

Selected characteristics regarding water, sanitation, hygiene, pre-intervention diarrheal disease, and wealth status for households in a randomized controlled trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from April of 2008 to February of 2009

	Control (N = 86)	Intervention (N = 90)	P value (χ^2 test)
Water collection frequency			
One to four times per week	16 (18.6%)	10 (11.1%)	0.15
Five or more times per week	69 (80.2%)	80 (88.9%)	0.15
Missing	1 (1.2%)	0 (0%)	0.15
Treat drinking water	16 (18.6%)	17 (18.9%)	0.38
Missing	0 (0%)	2 (2.2%)	0.38
Soap present	80 (93.0%)	86 (95.6%)	0.13
Missing	0 (0%)	2 (2.2%)	0.13
Latrine			
No latrine	47 (54.7%)	48 (53.3%)	0.83
Pit latrine	22 (25.6%)	21 (23.3%)	0.83
Pour-flush latrine	17 (19.8%)	21 (23.3%)	0.83
Dichotomous wealth			
Lower 40%	38 (44.2%)	35 (38.9%)	0.61
Upper 60%	33 (38.4%)	36 (40.0%)	0.61
Missing	15 (17.4%)	19 (21.1%)	0.61
Caregiver education level			
None	22 (25.6%)	23 (25.6%)	0.997
Any	64 (74.4%)	67 (74.4%)	0.997
Diarrhea in the last 7 days (pre-intervention)	N = 488 (112 < 5 years)	N = 532 (118 < 5 years)	
All ages	15 (3.1%)	15 (2.8%)	0.81
< 5 years	12 (10.7%)	11 (9.3%)	0.73

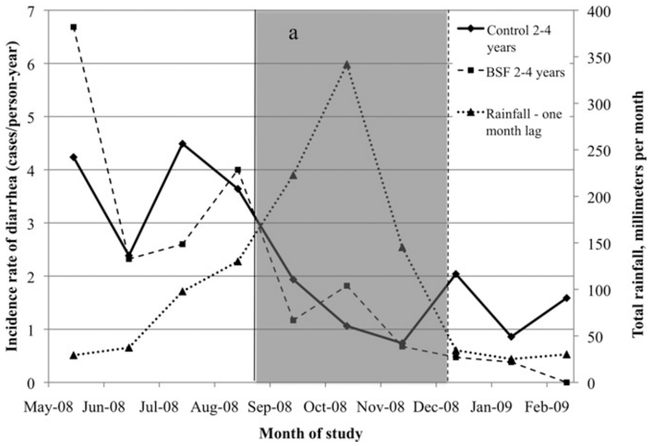

FIGURE 2. Monthly incidence of diarrhea (cases per person-year) in BSF intervention and control groups over the longitudinal study period from May of 2008 to February of 2009 and rainfall (mm/month) on a 1-month lag during a randomized controlled trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from May of 2008 to February of 2009. The solid vertical line indicates when BSFs were installed in the intervention homes, and the dashed vertical line indicates 100 days after installation. The gray-shaded area indicates the months that were considered the rainy season (July to October).

selected to receive plastic-housing BSFs (intervention households) experienced lower rates of diarrheal disease than control households, although the difference was not statistically significant (IRR = 0.83, 95% confidence interval [CI] = 0.62, 1.10). After plastic-housing BSF intervention, intervention households reported 0.73 times the diarrheal disease as control households (95% CI = 0.48, 1.12) for all age groups combined. In children 2–4 years old, both groups (BSF intervention and controls) had very similar levels of diarrheal disease before intervention (IRR = 1.06, 95% CI = 0.67, 1.67). However, after intervention, households with children aged 2–4 years were reported to have 0.57 times the diarrheal disease as children aged 2–4 years in control households (95% CI = 0.29, 1.13), a non-significant difference.

Logistic regression analysis. The effect of the plastic-housing BSF on diarrheal disease in families was also analyzed using a GEE extension of the logistic regression model to adjust for clustering within households. Covariates were assessed in a backward elimination process where all covariates were initially included. Variables were examined to determine whether they changed the effect of the plastic-housing BSF by 10%. Community location, water source, and categorical age remained in the model based on an *a priori* 10% change in effect criterion.[19] Results are presented in Table 4. Based on the GEE logistic regression model, the odds ratios of diarrheal disease do not indicate a statistically significant reduction for

TABLE 4

Results from GEE logistic regression model (adjusted for clustering among households) and odds ratios for diarrheal disease during BSF intervention of a randomized control trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from May of 2008 to February of 2009

	All ages		≤ 5 years old	
	Odds ratio*	95% CI†	Odds ratio*	95% CI†
Intervention	0.61	0.34–1.10	0.55	0.28–1.10

* OR with BSF as exposure.
† 95% CI for the OR.

all ages (0.61, 95% CI = 0.34, 1.10) or children under 5 years old (0.55, 95% = 0.28, 1.10), because the 95% CIs of the odds ratios span the null value of 1.0.

Water sources and water quality. Unprotected water sources were most used by study households for drinking water (49–69% households per month) followed by protected sources (24–50% per month), piped water (1–11% per month), and rainwater (0–2% per month).

The microbiological quality of water was analyzed and expressed as geometric mean MPN *E. coli* per 100 mL by source type and study period. Overall, *E. coli* concentrations in drinking water were highest in unprotected source water followed by protected source water (springs), piped water, and rainwater. Geometric mean *E. coli* concentrations of both unprotected and protected sources were > 100 MPN/100 mL during the pre-intervention period. Rain water and piped water had mean *E. coli* concentration that were consistently < 100 MPN/100 mL throughout the entire study period, although these sources constituted only a small percentage of household drinking water.

Water quality comparisons. Household source and drinking water qualities were compared over the entire study period for plastic-housing BSF intervention and control households. The geometric mean MPN *E. coli* and mean turbidities for the pre-intervention and intervention periods are compared in Table 5. Before the intervention, plastic-housing BSF intervention and control households had similar geometric mean MPN concentrations of *E. coli* both in their source and drinking water samples: 135 and 136 MPN/100 mL, respectively, for source water (P = 0.999, two-sample t test) and 122 and 123 MPN/100 mL (P = 0.986), respectively, for drinking water. These concentrations exceed the 100 *E. coli* MPN/100 mL microbial concentration considered high risk and unsafe according to WHO drinking water guidelines. During the intervention period, plastic-housing BSF intervention and control households had similar source water concentrations of *E. coli*: 60 and 54 MPN/100 mL, respectively (P = 0.400). However, the plastic-housing BSF group had drinking water (BSF-treated and BSF-treated and stored water) with a lower geometric mean *E. coli* concentration compared with control

TABLE 3

Unadjusted IRRs for diarrheal disease in BSF intervention and control households before and after BSF intervention stratified by age during a randomized controlled trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from May of 2008 to February of 2009

Data collection period	IRR* (95% CI)† all ages	IRR (95% CI) < 2 years	IRR (95% CI) 2–4 years	IRR (95% CI) ≥ 5 years
Before BSF	0.83 (0.62, 1.10)	0.86 (0.54, 1.37)	1.06 (0.67, 1.67)	0.59 (0.32, 1.08)
Intervention period	0.73 (0.48, 1.12)	0.78 (0.38, 1.59)	0.57 (0.29, 1.13)	0.89 (0.33, 2.39)

* IRR with BSF as exposure.
†95% CI for the IRR.

Table 5

Mean *E. coli* concentration and turbidity of source and drinking water for the control and BSF intervention groups before (from May to August of 2008) and after (from September of 2008 to February of 2009) plastic-housing BSF installation in a randomized controlled trial of the Hydraid plastic-housing BSF in Santa Rosa de Copan, Honduras, from May of 2008 to February of 2009

	Pre-BSF intervention			BSF intervention		
	Control	Intervention	*P*	Control	Intervention	*P*
Source water mean *E .coli** (MPN/100 mL)	136 (109, 169)	135 (109, 217)	0.999	53.7 (45.4, 63.6)	59.4 (50.5, 69.8)	0.400
Drinking water mean *E. coli**† (MPN/100 mL)	123 (98.9, 152)	122 (99, 151)	0.986	45.4 (38.6, 53.4)	23.4 (20.2, 27.0)	< 0.001
Source water mean turbidity (NTU)	38.0 (33.4, 43.2)	33.3 (29.1, 38.2)	0.166	22.6 (20.9, 24.4)	21.5 (19.9, 23.2)	0.367
Drinking water turbidity (NTU)*†	37.2 (32.5, 42.5)	33.0 (28.8, 37.9)	0.220	22.5 (21.0, 24.2)	20.7 (19.2, 22.4)	0.116

*Geometric means and 95% CIs per study period and *P* values from a two-sample unpaired *t* test with unequal variances.
†In most observations, the source and drinking water samples are the same for the control group, because few families treated their water.

households, with 23 and 45 MPN/100 mL, respectively ($P < 0.0001$). Thus, plastic-housing BSF households had drinking water that was of significantly better microbial quality than their source water (23 versus 60 MPN/100 mL), whereas the control group drinking and source waters were similar in microbial quality (45 versus 54 MPN/100 mL) and not significantly different. When water quality was analyzed as the main exposure, there was an association between odds of diarrheal disease and household drinking water quality. For every one unit increase in $\log_{10}$ concentration *E. coli*, there was 1.26 times increase in odds of diarrheal disease in all study participants over the entire period, and this finding remained a significant association when adjusted for participant age and clustering within households (odds ratio = 1.26, 95% CI = 1.08, 1.46).

During the pre-intervention period, BSF intervention and control groups had similar mean water turbidities: 33 and 38 nephelometric turbidity units (NTU), respectively, ($P = 0.17$) for source water and 33 and 37 NTU, respectively, ($P = 0.22$) for drinking water. After the plastic-housing BSF was installed, intervention and control groups had somewhat lower but still similar source water turbidities of 22 and 23 NTU, respectively, ($P = 0.37$), and drinking water mean turbidities of 21 and 23 NTU, respectively, ($P = 0.116$). In all cases, turbidities were greater than the five NTU maximum recommended by the WHO drinking water quality guidelines. The turbidity in drinking water samples was not found to have an effect on the odds of diarrheal disease in either study group in any part of the study (data not shown).

Plastic-housing BSF performance. The plastic-housing BSF achieved a mean 61% reduction of *E. coli* and a 38% reduction in total coliforms. However, when the influent water *E. coli* concentration was above 500 MPN/100 mL (172 samples), the geometric mean *E. coli* reduction was 1.17 $\log_{10}$ or 93.3%. The monthly mean *E. coli* reduction by the plastic-housing BSF was 36% in August (only weeks after installation) and then fluctuated between 53% and 69% reduction throughout the rest of the intervention period. The plastic-housing BSF minimally reduced turbidity by 3.8%. Mean turbidity reductions were < 5%, regardless of the influent water turbidity.

DISCUSSION

Effect of plastic-housing BSF on diarrheal disease. To our knowledge, this study is the first to assess the ability of the Hydraid plastic-housing BSF to reduce the incidence of household diarrheal disease as well as improve the microbial quality of household drinking water by reducing concentrations of *E. coli*. By multivariate analysis using a logistic regression model adjusted for clustering, households with a Hydraid plastic-housing BSF had a 39% lower risk of diarrhea compared with the control households for all age groups, a difference that was not statistically significant. The reductions in diarrheal disease found in this study, although statistically non-significant, are comparable in magnitude with statistically significant results from RCTs of concrete-housing BSFs in the Dominican Republic, Cambodia, and Kenya, which showed 47%, 47%, and 54% reductions in diarrhea, respectively, in children < 5 years of age.[9,12,13] The results of the GEE logistic model do not support the hypothesis that the Hydraid plastic-housing BSF was able to reduce self-reported diarrhea in this study.

There are several explanations for the lack of statistical significance found for the Hydraid plastic-housing BSF intervention in reducing the risk of diarrheal disease in children under 5 years. One obvious explanation, discussed in the next section, is that the plastic-housing BSF did not improve drinking water quality well enough in these communities to produce a statistically significant reduction in diarrheal disease. Another explanation could be that waterborne pathogens were not the only cause of diarrheal disease in the study communities. Many of the study communities had protected natural springs available for drinking water, and during certain months, up to 50% of study participants reported using protected springs as their primary water source. The source water qualities of both the control and intervention groups were 54 and 60 MPN *E. coli* per 100 mL respectively, lower than during the pre-intervention period and lower than the 100 MPN/100 mL microbial concentration considered high risk and unsafe according to WHO drinking water guidelines. Other fecal–oral routes of enteric pathogen transmission, including fomites, hands, or food, could have been the primary means of disease transmission in the study communities, in which case the BSF would not have been able to prevent the primary exposures causing transmission of diarrheal pathogens.

Diarrheal disease rates may have been similar in intervention and control households, because the quality of the water that the two groups were drinking may have been more similar than the water samples provided suggested. It is possible that BSF households were sharing filtered water with the control households or that BSF households were not using the BSF to treat their drinking water. However, study staff recorded during their visits whether the filter appeared to be in consistent use, and reports of disuse were rare and temporary. A more probable explanation is that the children under 5 years in BSF households may not have been drinking BSF-treated water. Young children may still have been breast-feeding, and school-aged children may have been drinking untreated water while at school. It was not appropriate to install BSFs in community schools during the study, because the intervention was performed at the household level. Perhaps a community-level intervention would have been more effective at ensuring that the intervention group more consistently drank BSF-treated water.

Diarrheal disease rates were much lower in both the control and BSF groups during the intervention period than the pre-intervention observation period. The power calculations were based on a 10% prevalence of diarrheal disease and an estimated 25% reduction in diarrheal disease with BSF use. A 10% prevalence of diarrheal disease is considered conservative compared with the 22% prevalence in Copan, Honduras, reported by the 2005–2006 Demographic Health Survey (DHS).[14] Because of the variability in the rates of diarrheal disease, a 6-month follow-up period may not have been sufficient to achieve statistical power in resolving differences in diarrheal disease between intervention and control households.

Seasonal variability of diarrheal disease should be taken into account in power calculations of future studies, and the intervention period in POU water treatment studies should be long enough to include seasonal differences in precipitation, temperature, and other factors possibly influencing diarrheal disease.

Diarrheal disease may have also been underreported because of participant fatigue or the difficulty for caretakers to remember disease events in the 7-day recall period. Although families may underreport diarrheal disease if recall is more than 48 hours, 7-day recall is common practice in rigorous studies of diarrheal disease and POU water treatment.[20,21] Participant fatigue, remote household location, and study expense made 48-hour visits impractical for this study. However, we recommend that future studies consider facilitating recall by providing and encouraging use of a simple daily diary of diarrheal disease in household members.[22,23]

Effect of the plastic-housing BSF on household drinking water quality. The mean *E. coli* concentration in drinking water from the intervention households was significantly lower than the concentration of the source water from those households and lower than the drinking water of the control group during the intervention period, but perhaps, it was not significantly different enough to reduce diarrheal disease significantly. Both of these comparisons show the ability of the Hydraid plastic-housing BSF to improve the quality of drinking water.

Although the BSF intervention group had a 51% lower mean *E. coli* concentration in drinking water samples than the control group, this finding is likely to be an underestimate of the true performance of the plastic-housing BSF. One reason for this underestimate is that the estimate of mean *E. coli* concentration in the control group includes samples of drinking water treated with chlorine or by boiling. No family in the plastic-housing BSF (intervention) group reported boiling or chlorinating water during the intervention. In addition, for plastic-housing BSF households, the drinking water quality parameters were expressed as the average of water directly from the BSF and stored BSF-treated water. Stored filtered water had higher concentrations of *E. coli* than water sampled directly from the filtrate outlet tube of the plastic-housing BSF, which could have been because of bacteria recontamination or regrowth.[24]

Within intervention households, the plastic-housing BSF achieved a mean 61% reduction of *E. coli* from source water. The reductions of *E. coli* reported here may not be representative of the true potential performance because of the relatively good microbial quality of the influent water. When the influent water *E. coli* concentration was above 500 MPN/100 mL, the geometric mean *E. coli* reduction was 1.17 $\log_{10}$ or 93.3%. This finding shows the *E. coli* reduction performance potential of the plastic-housing BSF when there are higher influent *E. coli* concentrations.

The turbidity of household drinking water in the BSF intervention group was not significantly different from the control group, suggesting that the Hydraid plastic-housing BSF did not improve turbidity of drinking water. This finding is contrary to past results in which it was documented that the concrete-housing BSF reduced turbidity by 82% in the field.[9] However, there exists relatively little peer-reviewed literature quantifying and reporting turbidity reduction by the concrete-housing BSF and even less for the plastic-housing BSF. More research is needed to better understand turbidity removal by the BSF, especially for different source waters having different kinds of turbidity from both anthropogenic and natural sources.

There was no trend in improved plastic-housing BSF performance for *E. coli* or turbidity reduction with time, and the flow rates decreased by only 18% over the 6-month intervention period. These findings suggest that the plastic-housing BSFs may have been maturing or ripening slowly. Past research has indicated that flow rate and BSF ripening have a significant effect of pathogen removal by the BSF.[11,25] Perhaps with the water quality and other environmental conditions of the study area, the ripening process was hindered, which affected performance. More studies comparing BSF flow rate, ripening, and performance in the field are needed.

Relationship between drinking water quality and diarrheal disease. Increased *E. coli* concentrations in drinking water were found to significantly increase odds of diarrhea disease by 26% for every $\log_{10}$ increase, regardless of intervention or study period. However, odds of diarrheal disease (comparing plastic-housing BSF and control groups) were lower during the dry season, suggesting that the plastic-housing BSF had a greater protective effect when source water quality had the lowest concentrations of *E. coli* of the entire study period and when the differences between the mean *E. coli* concentrations of BSF intervention and control groups were smallest. Thus, *E. coli* may not have been the best predictor of diarrheal disease risk because of the prevailing water quality conditions in this study area and time period. The work by Wright and others[26] found *E. coli* to be the least predictive of several bacterial indicators of fecal contamination. The work by Moe and others[27] found that diarrheal disease was correlated with diarrheal disease risk only with very high *E. coli* concentrations of > 1,000 *E. coli* per 100 mL.

In addition to possible deficiencies with the use of *E. coli* as an indicator of risk of diarrheal disease, the ability of the plastic-housing BSF to reduce *E. coli* most likely does not represent its ability to reduce other enteric pathogens like viruses and protozoa. Previous research has found a plastic-housing BSF to be much more effective at reducing protozoa such as *Cryptosporidium* oocysts, achieving a greater than 3 log reduction (99.9%).[28] Laboratory studies also show that the BSF is generally less effective at removing some viruses than *E. coli*.[11,25] Findings from these others studies provide evidence that *E. coli* reductions may not be accurately representing the microbial water quality of the study families or the microbial reduction performance of the plastic-housing BSF in this study.

Limitations of this study. In addition to the limitations discussed previously, it is important to note that the main limitation of almost all POU water treatment studies, including this study, is the lack of a placebo in the control group and a reliance on participant reporting of the disease outcome. The metaepidemiological study by Wood and others[29] of randomized control trials found that, in trials like our trial with self-reported outcomes and lack of blinding, the intervention effect can be exaggerated by about one-quarter (odds ratios = 0.75, 95% CI = 0.61, 0.93). We cannot rule out that responder and observer bias may have falsely increased the observed reduction of diarrheal disease. Both practical and ethical considerations limited the use of a placebo in this study, including the concern that users may change their water use behavior to switch from boiling or other treatment to using the (potentially placebo) filter, although we never discouraged other water treatments. Researchers have attempted to design a placebo filter but found challenges with creating a neutral filter and adequate participant blinding.[30] Almost all of the previously reported epidemiological field studies of household water treatment have also not used a placebo or been blinded.[20,31] It is possible that the results of this study are influenced by courtesy bias or that a placebo effect associated with the Hydraid BSF may have caused participants to underrecognize or underreport diarrhea. It is important to note that no blinded, placebo-controlled studies of HWT have yet shown a clear health benefit to study participants.[31] However, we show that participants in the intervention group had significantly lower levels of *E. coli* in their drinking water than the control group, which supports our hypothesis that lower diarrheal disease rates were at least in part because of an improvement in the microbiological quality of their drinking water. The work by Wood and others[29] found that, in studies with objective outcomes like drinking water microbiological quality, lack of blinding did not exaggerate the intervention effect; thus, we are confident that our reporting of the ability of the Hydraid BSF to reduce the microbial concentrations in drinking water was not influenced by a lack of blinding.

Despite these limitations, the results of this study can be compared with other rigorous studies of POU water treatment devices and their effect on diarrheal disease. These results confirm the results of past RCTs of the concrete-housing BSF by documenting that the Hydraid plastic-housing BSF has the ability to improve drinking water quality. However, these results do not document an ability to reduce diarrheal disease in households with a BSF, which has been previously reported, including in other trials of the Hydraid plastic-housing BSF.[9,12,13,32] The BSF in this trial was simultaneously tested in Cambodia with a similar study design—they found that, in households with a Hydraid plastic-housing BSF, participants had a 59% reduced risk of diarrheal disease (IRR = 0.41, 95% CI = 0.24, 0.69) and significant improvements in their water quality.[32]

It is important to note that, outside of this study, International Aid only promoted the Hydraid plastic-housing BSF in conjunction with safe storage and post-filtration chlorination. They provided chlorine with the plastic-housing BSF and taught participants the correct dosage for the safe storage vessel. No family with a BSF in this study chlorinated after filtering water, and it was not included in the BSF training before installation. Thus, the performance results from this study are most likely an underestimate of the water quality improvements and diarrheal disease reductions achieved by the Hydraid plastic-housing BSF when used in conjunction with post-filtration chlorination, which was recommended by the implementing organization.

Recommendations. Because this study is one of the first independent field studies of the performance of the Hydraid plastic-housing BSF, more research is needed to describe its performance and sustainability after installation. Performance of the Hydraid plastic-housing BSF varied widely during this study, and it did not significantly reduce diarrheal disease over the intervention period or significantly reduce the turbidity of drinking water. Past research has indicated that water dosing frequency, flow rate, and BSF ripening have a significant influence on pathogen removal by the filter.[11,25] More studies are needed to describe the effect of water dosing frequency, flow rate, ripening, and influent water quality on the performance of the Hydraid plastic-housing BSF in the field. Studies on the Hydraid plastic-housing BSF longevity are needed to ensure that they are durable and resistant to breakage beyond the 6-month follow-up period in this study. Investigating BSF use several months or years after installation is important to determine whether households continually and effectively use their Hydraid plastic-housing BSF and how well the plastic-housing BSF improves drinking water and lowers diarrheal disease risk over time.

Received January 31, 2011. Accepted for publication January 31, 2012.

Acknowledgments: The authors thank all of the study participants from the communities in Copan, Honduras, for their time and support during this study. The authors thank the interviewers and staff from Santa Rosa de Copan. We appreciate Kathy Tschiegg and Central American Medical Outreach for providing the office and laboratory space and the Honduras Office of International Aid for their logistical support during the study period. Thanks also to Douglas Wait and the University of North Carolina Environmental Microbiology Group.

Financial support: Laboratory supplies for water quality testing were generously provided by IDEXX laboratories and the Hach Company. We are also grateful to International Aid and Cascade Engineering for the financial support of this study. Although they provided financial support, they had no influence over the design of the study, analysis of the data, or interpretation of the results.

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